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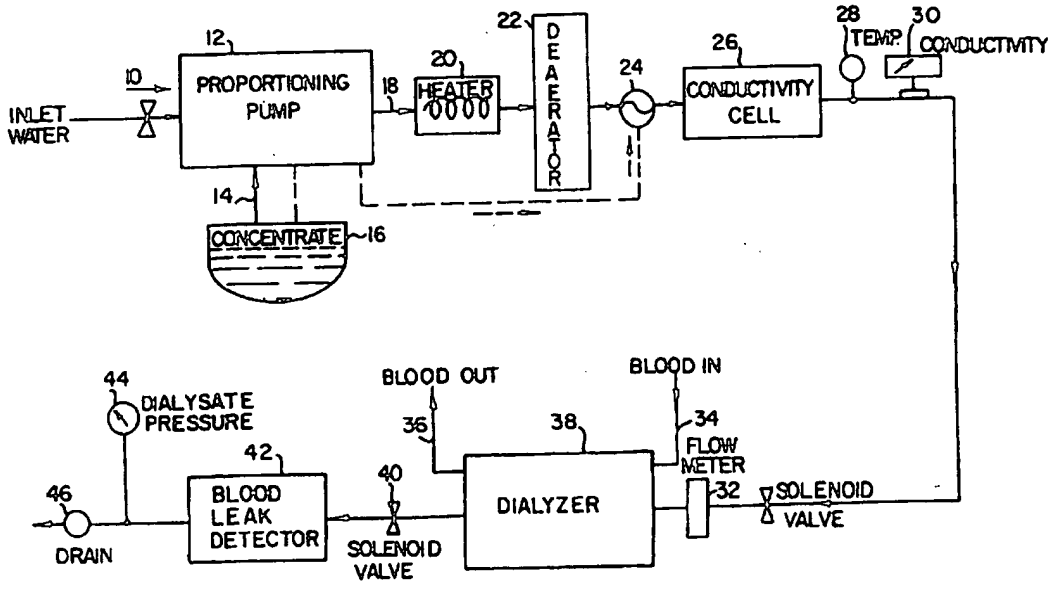

(57) Abstract

The present invention includes a method for the detection of blood leaks in a dialyzer (38) during high flux hemodialysis treatment. If the blood side pressure drops below the dialysate side pressure, the flow of dialysate to the dialyzer (38) is stopped. The ultrafiltrate flow rate is raised for a predetermined period of time to allow blood, if any, to flow across the membrane (52). The flow of dialysate is turned back on, and the dialysate flows past a blood leak detector (42).

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METHOD FOR DETECTING BLOOD LEAKS IN DIALYZER

FIELD OF THE INVENTION

Described herein is a method for the detection of blood leaks on a dialyzer during hemodialysis treatment. More specifically, a method for detection of blood leaks in a dialyzer during high flux hemodialysis treatment in the area of the dialyzer subject to backfiltration is disclosed.

BACKGROUND OF THE INVENTION

Hemodialysis is a form of treatment for chronic kidney failure. With hemodialysis, the patient's blood is purified outside the body in an artificial kidney called a dialyzer. A dialyzer contains a blood compartment and a dialysate compartment separated by a membrane. The total surface area of the membrane measures 1-2 square meters. During a hemodialysis treatment the patient's blood is allowed to flow on one side of the membrane and dialysis fluid on the other. At the beginning of the dialysis treatment, the waste product level in the blood is high, while the dialysis fluid contains no such products. Since the waste products are usually small dissolved substances they are able to move from the blood through the membrane and into the dialysis fluid. This movement continues until there is an equal level of the substances on both sides of the membrane.

For the movement of dissolved waste products, and consequently the purifying of the blood, to be effective throughout the entire treatment, newly mixed clean dialysis fluid flows continuously through the dialyzer on one side of the membrane. The process by

which dissolved substances move across the membrane in attempt to distribute themselves evenly in a solution is referred to as diffusion.

In order to remove excess water from the blood, it is necessary to create a pressure difference between the blood side and the dialysis fluid side of the membrane by means of suction pressure. This process is referred to as ultrafiltration.

It is readily understood that many safety features need to be built into a system that delivers hemodialysis treatment to a patient. One such safety feature includes a blood leak detector, capable of detecting if there is a defect in the membrane, thus allowing for blood to leak from the blood side to the dialysis side. Typically, hemodialysis delivery systems incorporate a sensor, usually of the photo-optical type, that can detect the presence of blood in dialysate. Because the dialysate's osmolarity is not very different from that of blood, the red cells are not hemolyzed. Detecting the blood leak is usually accomplished by measuring the change in optical transmission caused by the scattering of light by hemoglobin-containing red cells in the dialysate stream. The blood leak sensor is usually of the flow through type, and the threshold of detection is adjustable. In some systems the magnitude of the leak is calibrated in units of milliliters of blood in liters of dialysate. Other systems have an index to represent the relative magnitudes of the leak with no quantization. In the event of a blood leak, detected at the threshold chosen, alarm circuits that interrupt power to the blood pump are activated. In addition, in some systems, the flow of dialysate by-passes the dialyzer.

Blood leak detectors come in many forms, as indicated in the prior art. For example, U.S. Patent 4,181,610 of Shintani et al. discloses a blood leak detector which has an optical portion comprising a measurement cell through which dialysis solution under test passes, an alternately energized pair of light-emitting diodes positioned on one side of the cell, and a photo sensitive detector positioned at the opposite side of the cell and close thereto. One light emitting diode emits radiation at longer wavelengths while the other emits radiation at shorter wavelengths. Both the diodes are adjusted to produce photo detecting signals at the same level when no blood exists in the cell. The photo detecting signals at the photosensitive detector are detected and analyzed to give signals deflected in one direction in proportion to the degree of blood leak when it has occurred. When bubbles are detected, they give signals in the opposite direction, based on the fact that blood absorbs light mainly at shorter wavelengths while bubbles mainly at longer wavelengths.

U.S. Patent 4,017,190 of Fischel discloses a system for detecting small amounts of hemoglobin in a solution by detecting the ratio between the light transmissivities at separated wavelengths of a sample solution, one of which wavelengths is in a range at which hemoglobin is highly light absorptive. Through the use of the ratios of the signals, a reading of high sensitivity and linearity is provided in the presence of substantial contamination and turbidity in the sample or the system.

U.S. Patent 3,832,067 of Kopf et al. discloses a colorimeter for detecting blood leaks in an artificial kidney machine. The colorimeter senses the presence of a contaminant opaque to light of a specific color which is

carried in a fluid flowstream. As the flowstream passes through the colorimeter, a photocell on one side of the flowstream is illuminated only by light of the specific color which originates on the opposite side of the flowstream, the photocell sensing a change in intensity of transmitted light is caused by presence of the contaminant.

U.S. Patent 3,900,396 of Lamadrid teaches a blood leak detector that consists of a transparent conduit through which dialysate circulates through a block. The block contains a lamp whose light passes through a first channel in the block transversely intersecting the conduit and a second channel in the block at an angle to the first channel and about the same length, avoiding the conduit. Identical 550-560 mm filters and photovoltaic cells are provided at the ends of the channels. The channels provide relatively wide dispersion angles. Circuitry is provided to measure the differential response of the photovoltaic cells and express this in terms of a voltage. An excessive difference between this voltage and a reference voltage will operate an alarm or an emergency device.

U.S. Patent 4,060,485 of Eaton discloses a dialysis apparatus employing what is described as a conventional type blood leak detector, one containing photoelectric means for detecting the presence of blood in brine solution which indicates leakage or malfunction of the dialysis unit. Upon detection of a blood leakage, the leak detector sends an electronic signal to logic electronics which activate a signal lamp or audible means to indicate that a blood leakage has occurred.

A limitation of the blood leak detectors found

in the prior art is in the ability to detect a blood leak during high flux dialysis treatment. High flux dialysis treatment is needed at certain times as prescribed to meet the needs of an individual patient. During high flux dialysis treatment, the membrane in the dialyzer has a much higher rate of diffusion. This higher rate of diffusion may create a condition where the blood side pressure becomes negative in relation to the dialysate side pressure. This is referred to as backfiltration because in this portion of the dialyzer, dialysate is sterile filtered by the dialyzer membrane and passes into the blood stream.

The amount that backfilters during the dialysis treatment is a function of the rate of ultrafiltration prescribed and is controlled by the volume concentrate of the equipment. When a blood leak occurs during backfiltration however, the leak is from dialysate to blood side, and the blood leak sensor of the machine never detects the leak because there is no blood in the dialysate to detect.

It is readily understood that there may be serious implications to the patient if this condition were to occur. The risk of running a dialyzer with a leak in the backfiltration region is that if heavily contaminated dialysate is used during the treatment, anywhere from 50 to 100 cc's of contaminated water could enter the patient without knowledge, resulting in pyrogenic reactions or bacteremias.

SUMMARY OF THE INVENTION

The present invention provides a method for the detection of blood leaks during high flux dialysis

treatment. More specifically, this invention allows for the automatic testing of the high flux dialyzer for membrane leaks in the area of backfiltration.

The method of blood leak detection in accordance with this invention is comprised generally of the following steps, while performing hemodialysis treatment on a patient in the conventional manner. First, the flow of dialysate in the dialysate side of the artificial kidney is automatically turned off. The ultrafiltrate flow rate through the dialyzer is then increased to a value which is greater than 500 ml/min for a period of time greater than 20 seconds. This allows the for the blood side pressure in the dialyzer to return positive with reference to the dialysate side pressure. Additionally, if there is a leak in the membrane, this allows time for a sufficient amount of blood to pass through the leak to the dialysate side of the dialyzer.

Once the 20 second period with ultrafiltration is expired, the flow of dialysate to the dialyzer is turned back on. Hemodialysis treatment continues and the dialysate then flows from the dialyzer through the machine's blood leak detector. If there has been a blood leak, this step now allows the blood concentrated ultrafiltrate to pass through the machine's blood leak sensor and any blood in the dialysate flow can be detected.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic representation of a single pass, single patient hemodialysis system.

FIG. 2 is a flow diagram of a hemodialysis

circuit.

FIG. 3 is a graph representing low flux hemodialysis pressure gradients.

FIG. 4 is a graph representing high flux hemodialysis pressure gradients.

FIG. 5 is a flow chart of the method of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Hemodialysis treatment which is controlled and monitored by a dialysis machine is best understood with reference to FIG. 1, which is a schematic representation of a single pass, single patient dialysis delivery system. It is readily understood that the method of this invention may be practiced with other types of dialysis delivery systems such as recirculating single pass systems, recirculating systems, single patient or multiple patient systems. However, for the purpose of this disclosure, the method of this invention will be described in conjunction with the single pass, single patient dialysis delivery system.

Prior to the start of dialysis treatment, the entire system is rinsed and made free of air. The patient is connected to the machine by connecting the blood lines, blood in 34 and blood out 36, to needles positioned in the patients forearm. Blood is then pumped from the patient, through the dialyzer, and back to the body via blood lines.

The proportioning pump 12 controls the mixture

of the dialysis fluid. Here, water 10 is mixed with a concentrated salt solution 14 to the correct chemical composition. The fluid then passes to a heater 20 which ensures that the fluid temperature is heated to body temperature before it is pumped to the dialyzer.

Since the incoming feed water to the delivery system usually has a considerable amount of dissolved air it needs to go through a deaerator 22 to remove the air from the solution. The deaeration of dialysate in delivery systems is achieved by having the heated incoming water subjected to extreme negative pressures (usually 300 to 600 mm Hg) and then venting the air which is released from the solution.

The conductivity cell 26 is commonly used to monitor appropriate proportioning water and liquid concentrate to ensure proper dilution of the solution. Temperature 28 and conductivity 30 are monitored with both display and alarm devices to indicate proper functioning before the dialysate is passed into the dialyzer.

A flow meter 32 monitors the flow rate of the dialysate as it enters the dialysate side 48 of the dialyzer 38. The importance of the ratio between the flow rate of dialysate to the flow rate of blood in the dialyzer according to the practice of this invention will subsequently discussed.

The dialysate is then passed out of the dialyzer 38 past a blood leak detector 42 which is programmed to detect the presence of blood in dialysate. Typically, a photo-optical sensor is incorporated in the blood leak detector which can measure the change in

optical transmission caused by the scattering of light by hemoglobin containing red cells in the blood stream, now contained in the dialysate. It is understood that any type of blood leak detector known in the art which is suitable for detection of blood in dialysate solution may be used in accordance with the present invention. In the event of a blood leak, alarm circuits that interrupt power to the blood pump are activated, and in some systems, the flow of dialysate by-passes the dialyzer. Finally, the dialysate flows from the blood leak detector 42 out to the drain 46.

In hemodialysis treatment, blood flows from the patient, through the blood compartment 50 and back to the patient though the blood lines depicted which are in FIG. 1, while newly mixed, clean dialysis fluid flows continuously through the dialysate compartment 48.

The process by which the blood is purified in the dialyzer 38 is best described with reference to FIG. 2. The dialyzer 38 consists of a blood compartment 50, a dialysate compartment 48, and a semi-permeable membrane 52 that separates the compartments. Waste products in the blood, usually small dissolved substances, are able to move from the blood flowing in the blood compartment 50, through the semipermeable membrane 52 and into the dialysate compartment 48.

The membrane 52 which separates the two compartments is a semipermeable membrane with a typical surface area that measures 1 to 2 square meters. Although such membranes are of a great variety, they are all characterized by the fact that they allow one component of a solution to pass through them and prevent the passage of another component. During the treatment,

blood is allowed to flow on one side of the membrane, while dialysis fluid flows on the other. During standard hemodialysis treatment, the flow rate on the blood side is typically 100 ml/min while the flow rate on the dialysate side typically ranges from 200 ml/min to 500 ml/min for the average adult.

In order to remove excess water from the blood, it is necessary to create a pressure difference between the blood side 50 and the dialysis fluid side 48 of the membrane. This characteristic, attributable to the phenomenon of osmosis, is typically referred to as ultrafiltration.

Any osmosis apparatus depends on the separation of a solution from its pure solvent by means of a membrane, permeable to the solvent but impermeable to the solute (here the blood and dialysis solutions). When such an arrangement is made, it is found that there is a natural tendency for the solvent to flow from the pure solvent chamber through the membrane into the solution chamber. This tendency can be opposed by applying pressure, referred to as osmotic pressure, to the solution chamber.

In standard hemodialysis treatment, pressure gradients in the dialyzer are such that the blood side pressure throughout the dialyzer is positive relative to dialysate pressure so if a leak were to occur in the membrane, the leak would be from blood side to dialysate side. Thus, as the dialysis fluid flows from the dialyzer through the blood leak detector, the leak would be detected. The pressure gradients in standard or low flux dialysis treatment are depicted by FIG. 3.

Depending upon the needs of different patients, it is often necessary to change the rate of ultrafiltration during dialysis treatment. It may be necessary to raise the rate of ultrafiltration and reduce the period of time for treatment. In doing so, it is possible for the blood side pressure to become negative in relation to the dialysate side pressure. The pressure gradients in high flux dialysis treatment are depicted by FIG. 4.

This situation, illustrated by the graph in FIG. 4, which applies osmotic pressure on the compartments, is referred to as backfiltration because dialysate is sterile filtered by the dialyzer membrane and passes into the bloodstream. When this type of leak occurs, dialysate leaks from the dialysate side into the bloodstream, thus there is no blood in the dialysate as it flows from the machine through the blood leak detector that would indicate the leak.

If this situation were to go undetected, possibly 50 to 100 cc's of contaminated water could enter the patient without knowledge, which may result in pyrogenic reactions of bacteremias.

The automatic testing of the high flux dialyzer for membrane leaks in the area of backfiltration may be done according to the method of this invention that is described as follows, and as shown in the flow diagram of FIG. 5. First, high flux hemodialysis dialysis treatment is started on a patient. If, during the treatment, it is determined that the blood side pressure has become negative relative to the dialysate side, the dialysate flow is automatically turned off.

Next, the ultrafiltrate flow rate is raised to a value greater than 500 ml/min for a period of greater than 20 seconds.

Once the blood side pressure returns to positive, the dialysate flow to the dialyzer is turned on. The dialysate then flows out of the machine past the blood leak detector.

If there is a leak in the membrane, the 20 second period with ultrafiltration should be sufficient to allow blood to pass through the membrane into the dialysate. Then, the blood concentrated ultrafiltrate passes by the blood leak sensor which indicates the leak.

WE CLAIM:

1. A method for detection of blood leaks during high flux hemodialysis treatment, said method comprising the steps of: engaging a dialysis patient with an artificial kidney, said artificial kidney comprising a blood compartment through which said patients blood flows, a dialysate compartment through which dialysate solution flows and a semipermeable membrane therebetween, said artificial kidney also including means for monitoring pressure within said compartments and a blood leak detector; performing hemodialysis treatment on said patient; and testing the semipermeable membrane for leaks if the blood compartment pressure falls below the dialysate compartment pressure.

2. The method of claim 1, wherein said testing step is further comprised of: stopping the flow of dialysate to the dialysate compartment of the artificial kidney; raising the pressure of the blood compartment to a positive value as compared to the pressure of the dialysate compartment; and restarting the flow of dialysate to the dialysate compartment of the artificial kidney.

3. The method of claim 2, wherein said artificial kidney further comprises a controller for controlling the pressure in said compartments and controlling the ultrafiltrate flow rate across said membrane, and wherein said step of raising the pressure of the blood compartment is comprised of increasing the ultrafiltrate flow rate for a set period of time.

4. The method of claim 3, wherein the

ultrafiltrate flow rate is increased to a value greater than 500 ml/min.

5. The method of claim 4, wherein the ultrafiltrate flow rate is increased for a time period of 20 seconds or more.

6. The method of claim 5, further comprising the step, after said restarting step, of checking said dialysate solution for the presence of blood by allowing the dialysate solution to flow past the blood leak detector in the artificial kidney.

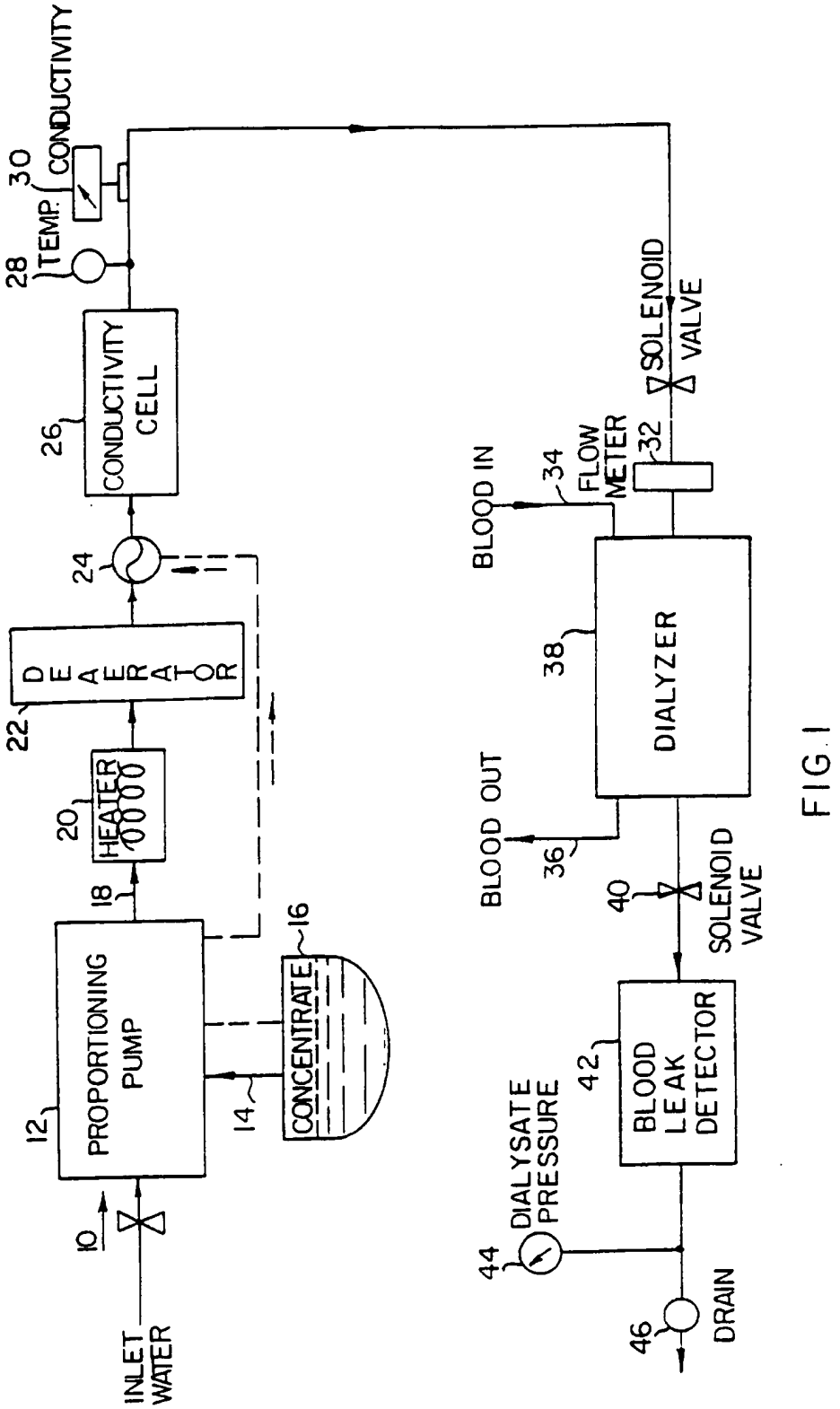
INLET WATER
10
PROPORTIONING PUMP
12
CONCENTRATE
14
16
18
HEATER
20
DEAERATOR
22
24
CONDUCTIVITY CELL
26
TEMP.
28
CONDUCTIVITY
30
SOLENOID VALVE
32
FLOW METER
34
BLOOD IN
DIALYZER
38
BLOOD OUT
36
40
SOLENOID VALVE
BLOOD LEAK DETECTOR
42
DIALYSATE PRESSURE
44
DRAIN
46

FIG. 1

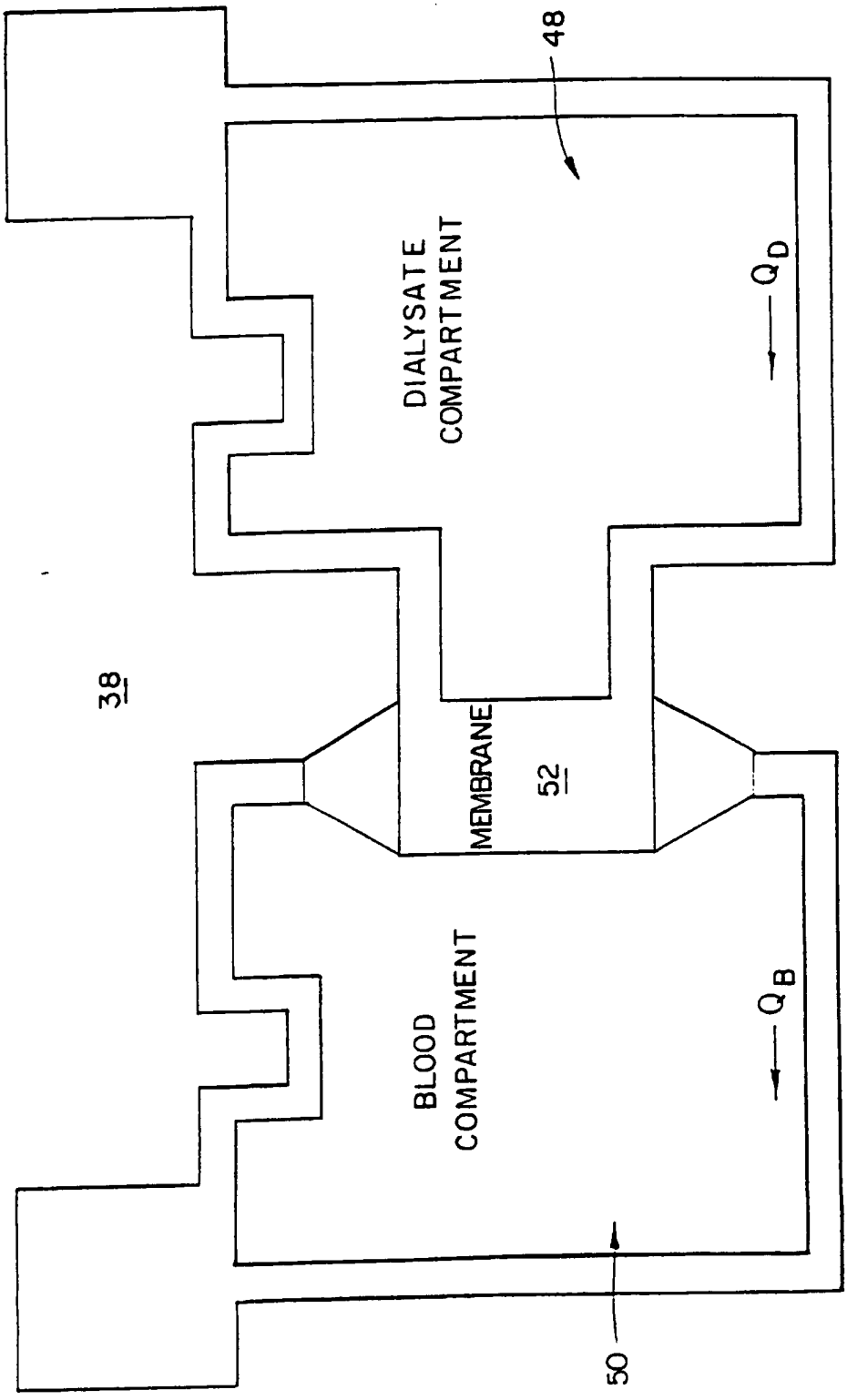
48
DIALYSATE COMPARTMENT
Q_D
38
MEMBRANE
52
BLOOD COMPARTMENT
Q_B
50

FIG. 2

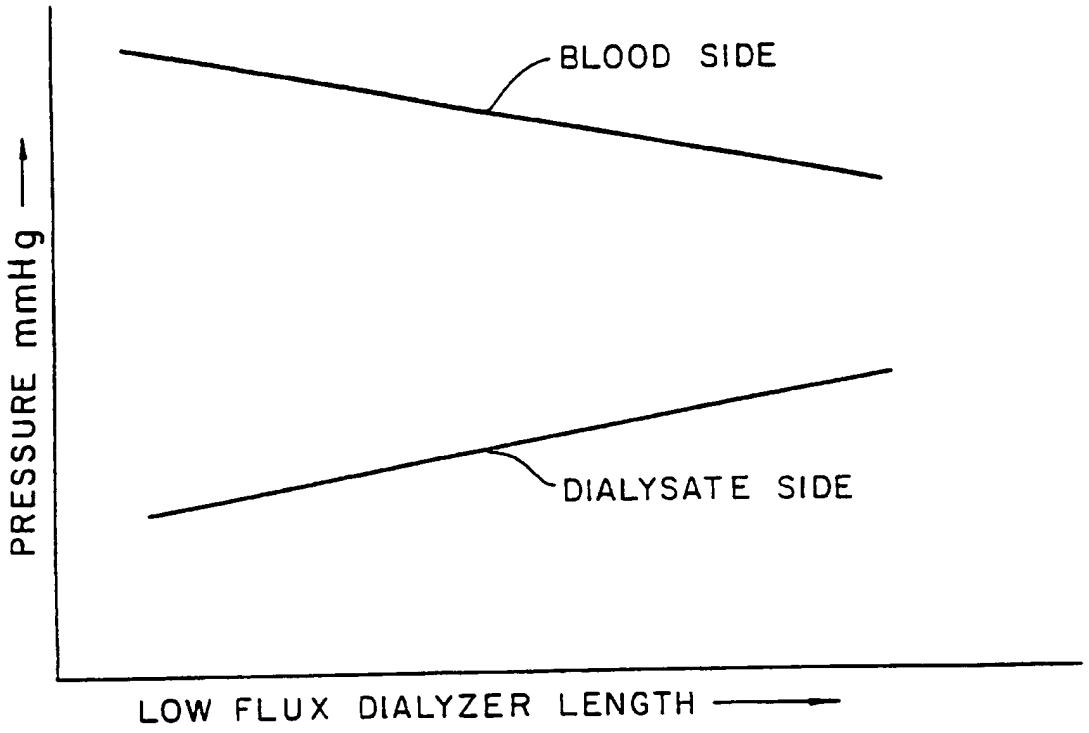
BLOOD SIDE
DIALYSATE SIDE
PRESSURE mmHg
LOW FLUX DIALYZER LENGTH

FIG. 3

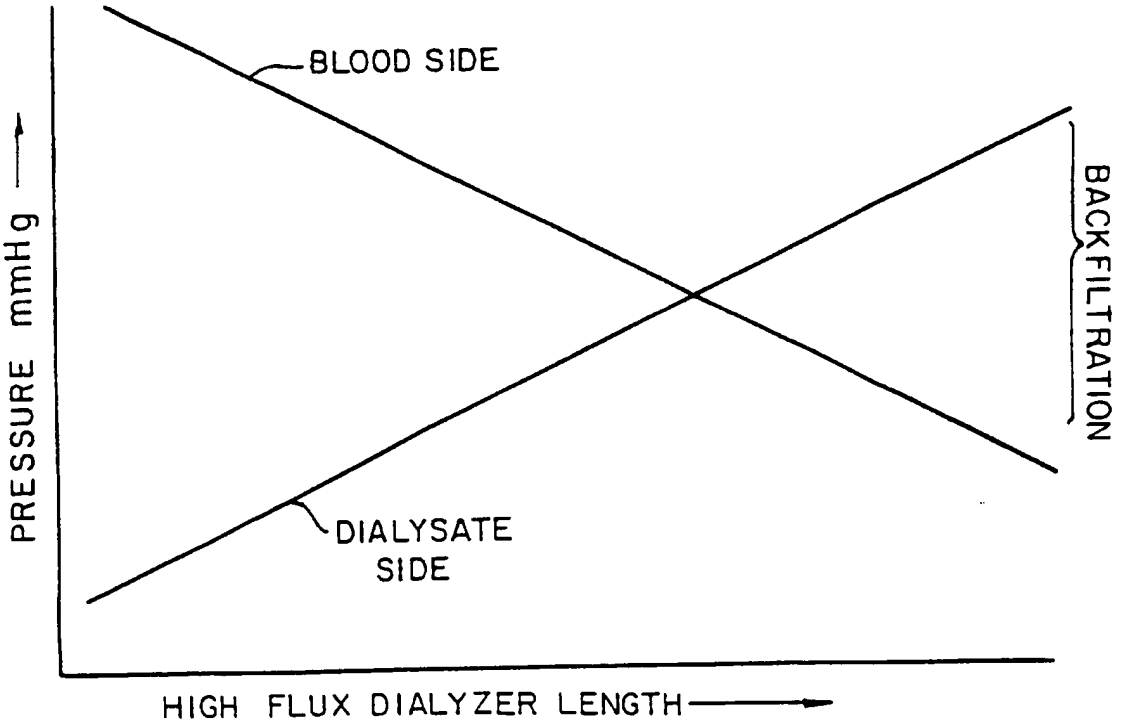
BLOOD SIDE
DIALYSATE SIDE
BACKFILTRATION
PRESSURE mmHg
HIGH FLUX DIALYZER LENGTH

FIG. 4

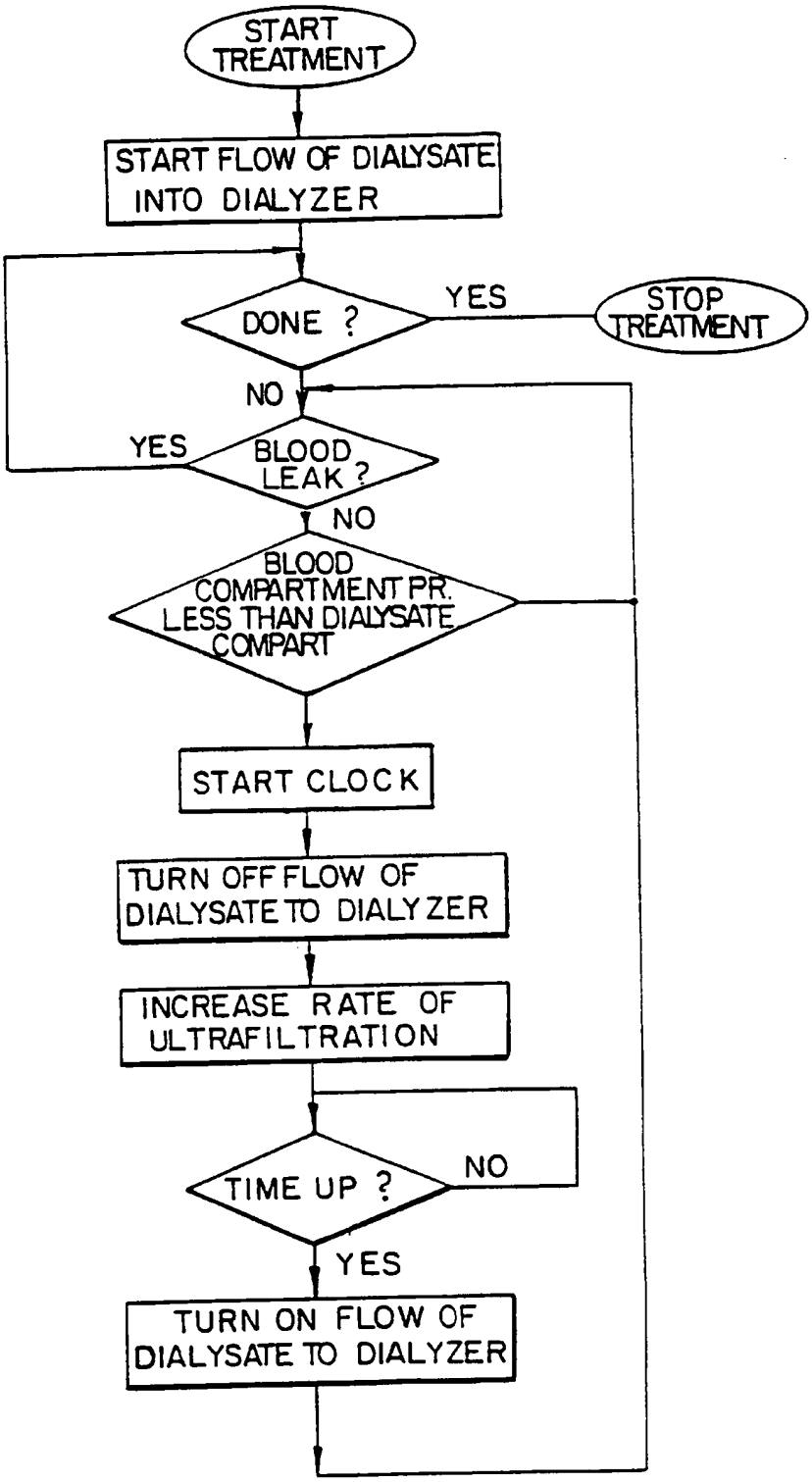
START TREATMENT
START FLOW OF DIALYSATE INTO DIALYZER
DONE ?
YES
STOP TREATMENT
NO
YES
BLOOD LEAK ?
NO
BLOOD COMPARTMENT PR. LESS THAN DIALYSATE COMPART
START CLOCK
TURN OFF FLOW OF DIALYSATE TO DIALYZER
INCREASE RATE OF ULTRAFILTRATION
TIME UP ?
NO
YES
TURN ON FLOW OF DIALYSATE TO DIALYZER

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/15529

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B01D 61/32, 61/34, 65/10

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 210/85, 90, 97, 321.65, 321.69, 321.72, 645, 646, 650, 651, 739, 741, 929; 73/38, 40

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,990,973 A (J.T. BOAG ET AL) 09 NOVEMBER 1976 (09.11.76), see entire document.	1-3
Y	DE 3442744 C2 (H.D. POLASCHEGG) 05 JUNE 1986 (05.06.86), see entire document.	1-6

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Date of the actual completion of the international search	Date of mailing of the international search report
31 OCTOBER 1996	13 NOV 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer SUN UK KIM Telephone No. (703) 308-2350

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

In...national application No.
PCT/US96/15529

A. CLASSIFICATION OF SUBJECT MATTER:
US CL :

210/85, 90, 97, 321.65, 321.69, 321.72, 645, 646, 650, 651, 739, 741, 929; 73/38, 40